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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 2005_0747A

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/534,423	05/10/2005

First Named Inventor: Yasuo HAYASHI et al.

Art Unit	Examiner
1619	Christopher Raymond Lea

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEES FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 55,540
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

WALTER C. PLEDGER
Typed or printed name

202/721-8200
Telephone number

November 16, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	Attorney Docket No. 2005_0747A
Yasuo HAYASHI et al.	:	**Confirmation No. 4714**
Serial No. 10/534,423	:	Group Art Unit 1619
Filed May 10, 2005	:	Examiner Christopher R. Lea
METHOD FOR PRODUCING ORALLY ADMINISTRABLE EDIBLE AGENT OF LAMINATE FILM FORM AND PRESSURE BONDING APPARATUS OF THE AGENT	:	**Mail Stop: AF**

REMARKS IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Sir:

Further to the Notice of Appeal submitted herewith, and prior to submission of the required Appeal Brief, kindly consider the following remarks regarding the pending rejections.

In the final Office Action of July 16, 2009, the Examiner rejected claims 39-76 under 35 U.S.C. § 103(a) as being unpatentable over Roreger et al. (WO 02/51815 (in German) using U.S. 6,818,087 as a translation) in view of Nogami (WO document 02/87622 (in Japanese) using U.S. 2004/0137040 as a translation). For the reasons discussed below, it is respectfully submitted that the present claims are clearly patentable over the prior art of record.

Independent claims 39, 49, 56 and 62 each recite a method for producing an orally administrable edible agent of laminate film form. The methods of claims 39, 49, 56 and 62 include: (1) forming a plurality of orally administrable edible agent layers, wherein *each orally administrable edible agent layer is formed on a surface of a respective resin film* by coating and drying; (2) joining together two orally administrable edible agent layers so that orally administrable edible agent layer surfaces face each other and the orally administrable edible agent layers are sandwiched between corresponding resin films of the two orally administrable

edible agent layers; and (3) *delaminating only one of the two resin films* by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls.

Roreger discloses a method for producing a laminated sheet matrix which contains a releasable ingredient. In particular, Roreger discloses that an active ingredient is applied to a base layer 1 by an applicator nozzle 12, and that a base layer 2 is laminated on the base layer 1 so as to seal the active ingredient within the base layers 1, 2 for maturation. Further, Roreger discloses that each base layer 1, 2 includes protective layers 3, 4 which may be detachable.

Initially, it is noted that independent claims 39, 49, 56 and 62 recite forming a plurality of orally administrable edible agent layers, wherein each orally administrable edible agent layer is formed on a surface of a respective resin film. In this regard, it is noted that Roreger discloses that the active substance is applied to a surface of at least one of the base layers 1 and 2 (see column 3, lines 36-37). Thus, in the response filed on May 5, 2009, it was noted that the base layers 1 and 2 of Roreger correspond to the resin films of the claimed invention (*i.e.*, the films on which the edible agent layers are formed), and that Roreger does not disclose or suggest delaminating only one of the two "resin films" as required by independent claims 39, 49, 56 and 62, because Roreger discloses that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (see column 5, line 66 through column 6, line 5).

However, during the telephone interview of October 8, 2009, the Examiner clarified that the layers 1 and 2 are being interpreted as also including the active ingredient, and are thus being interpreted as the "edible agent layers" of independent claims 39, 49, 56 and 62, and that the protective films are being interpreted as the "resin films" of independent claims 39, 49, 56 and 62.

In this regard, it is first noted that Roreger clearly discloses that reference numbers 1 and 2 correspond to layers of the matrix base material, that the active substance is applied to at least one of the layers 1, 2, and that both base material layers 1, 2 (and not the active ingredients) are joined together such that the active substance medium does not emerge at the edges of the weblike matrix 14 and such that the interfaces of the base material layers 1, 2 are bonded inseparably, as shown in Fig. 2 (see column 3, lines 36-37; column 4, lines 38-39; and column 5, line 66 through column 6, line 5). Thus, as Roreger clearly discloses that the reference numbers

1 and 2 correspond to the base material layers, and that the active substance is formed on the layers 1 and 2 as shown in Fig. 2, it is respectfully submitted that the layers 1 and 2 do not constitute the edible agent layers of claims 39, 49, 56 and 62. Rather, it is respectfully submitted that the layers 1 and 2 correspond to the resin films of the claimed invention (*i.e.*, the films on which the edible agent layers are formed.

Further, even if the interpretation of the base material layers 1 and 2 as the edible agent layers is proper and the interpretation of the protective layers 3 and 4 as the resin layers of independent claims 39, 49, 56 and 62 is proper, Roreger does not disclose *delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers* in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 39, 49, 56 and 62.

Rather, Roreger discloses that protective layers 3 and 4 are removed from the base layers 1 and 2 prior to application of the active substance (column 4, lines 46-49). Thus, Roreger does not disclose delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers, as required by independent claims 39, 49, 56 and 62, because Roreger discloses that the protective layers 3 and 4 are removed prior to the application of the active substance and therefore do not sandwich the active substance.

For the same reasons discussed above, it is also noted that Roreger does not disclose or suggest a pressure bonding apparatus which includes a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers, as required by independent claim 69.

Further, as noted by the Examiner on page 6 of the Office Action, Roreger does not disclose an orally administrable edible agent of laminate film form. In this regard, the Examiner cites Nogami as disclosing a layered edible film for administering an active agent, and concludes that it would have been obvious to one of ordinary skill in the art to make the layered edible film of Nogami by the method of Roreger so as to arrive at the claimed invention.

Nogami discloses an orally administered agent which includes a combination of drug-containing layers 11, water-swellable gel-forming layers 12, and intermediate layers 13. On page 9 of the Office Action, the Examiner cites paragraph [0113] of Nogami as disclosing the removal of a support film from the orally administered agent, and notes that the determination of

when to remove the support film and which films to remove are certainly within the purview of the skilled artisan.

However, it is noted that MPEP § 2143.01(V) states that a proposed modification cannot render the prior art unsatisfactory for its intended purposed. As indicated above, Roreger discloses an active ingredient layer formed on base layers 1 and 2, and that the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably (see column 5, line 66 through column 6, line 5). Thus, modifying the Roreger reference by removing one of the films on which the orally administrable edible agent layer is formed (*i.e.*, base layers 1 and 2) would render Roreger unsatisfactory for its intended purpose, as Roreger explicitly discloses the base layers 1 and 2 are irreversibly bonded, and that it is necessary that the interfaces of the base layers 1 and 2 are bonded inseparably. Accordingly, one of ordinary skill in the art would not have modified the Roreger reference by removing one of the base layers 1 and 2, as Roreger explicitly teaches away from such a modification.

Further, with regard to the Examiner's interpretation of the protective layers 3 and 4 as the resin layers of independent claims 39, 49, 56 and 62, it is noted that Roreger only discloses that protective layers 3 and 4 are removed from the base layers 1 and 2 prior to application of the active substance (column 4, lines 46-49), and prior to the laminating unit 13, as shown in Fig. 1, and therefore does not disclose a method which includes delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 39, 49, 56 and 62.

In this regard, paragraph [0113] of Nogami merely discloses that the administered agent is "peeled off" of the support film, and does not disclose or even remotely suggest delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 39, 49, 56 and 62. Accordingly, as none of the Roreger and Nogami references discloses or suggests delaminating only one of the two resin films by conveying the two resin films sandwiching the bonded orally administrable edible agent layers in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claims 39, 49, 56 and 62, it is respectfully submitted that

one of ordinary skill in the art would not have modified Roreger in view of Nogami so as to result in or render obvious the invention of claims 39, 49, 56 and 62.

For the same reasons discussed above, it is also noted that Roreger and Nogami do not disclose or suggest a pressure bonding apparatus which includes a winding shaft arranged to draw and delaminate only one of the two resin films sandwiching the orally administrable edible agent layers, and a delamination roll disposed at a position forward of the pair of press rolls in a conveying direction of the pair of press rolls and in a substantially tangential direction at a pressurization zone of the pair of press rolls, as required by independent claim 69.

Therefore, for the reasons presented above, it is believed apparent that the present invention as recited in independent claims 39, 49, 56, 62 and 69 is not disclosed or suggested by the Roreger reference and the Nogami reference taken either individually or in combination. Accordingly, a person having ordinary skill in the art would clearly not have modified the Roreger reference in view of the Nogami reference in such a manner as to result in or otherwise render obvious the present invention of independent claims 39, 49, 56, 62 and 69.

Therefore, it is respectfully submitted that independent claims 39, 49, 56, 62 and 69, as well as claims 40-48, 50-55, 57-61, 63-68 and 70-76 which depend therefrom, are clearly allowable over the prior art of record. Accordingly, it is respectfully requested that the outstanding rejections be withdrawn, and that a Notice of Allowance be issued in this application.

Respectfully submitted,

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